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**High Incidence Cohort of IDUs  
Exposed to Infection with HIV of Low  
Genetic Diversity  
for HIV Vaccine Efficacy Trials**

**A.P.Kozlov  
The Biomedical Center and  
St.Petersburg University  
St. Petersburg, Russia**



# HPTN 033 study (2002 – 2004)

## Objectives

- Estimate HIV prevalence and incidence in a cohort of IDU
- Estimate the possibilities for conducting long term prevention trials and interventions in high risk groups, incl. determining the best recruitment and retention strategies (cohort development)



# Socio-Demographic Characteristics

	<b>Screened</b> (n = 900)	<b>Enrolled</b> (n = 520)
<b>Gender:</b> male/female	<b>71/29%</b>	<b>70/30 %</b>
<b>Median Age (range):</b>	24.0 (17 – 42)	24.5 (17 – 42)
<b>Marital Status:</b> Single Married	68 % 5 %	67 % 5 %
<b>Education:</b> With university/vocational school	49 %	50 %
<b>Employment:</b> Unemployed	43 %	43 %
<b>Housing:</b> Stays with parents/relatives	70 %	68 %



## HPTN 033 Baseline results

<b>Total amount of screened</b>	<b>HIV + (%)</b>	<b>Indeterminate WB</b>
<b>900</b>	<b>270 (30)</b>	<b>13 (0,9)</b>



# Retention in HPTN 033 cohort for the 12 month follow up period

Retention at 6-month	80% (417/520)
Retention at 12-month	79% (413/520)
Adjusted retention	89,4%(465/520)
# of Deaths	11 (2,1%)
# of Hospitalization	3 (0,6%)
# of Incarceration	32 (6,2%)



# HIV Incidence in HPTN 033 cohort

- **Number of seroconversions during 12 months FUP:**  
**20 (8 (42%) at 6 months FU)**
- **HIV incidence in a cohort:**  
4.5 per 100 p-y
- **Factors significantly associated with incidence:**  
injection use of psychostimulants (ephedrine based and amphetamines)  
 $\geq 3$  sexual partners in last 6 months



# HIV Prevalence and Incidence among IDU Participants of Different Projects at Biomedical Center

Study (Years)	HIV status at screening		Prevalence (%)	Incidence by STARHS/BED	Incidence in Cohort
	Pos	Neg			
HPTN 033 Cohort (2002-2004)	270	617	<b>30</b>	4.8 ± 2.7 % by STARHS	4.5 per 100 p-y [95% CI. 2.7, 7.0]
R01 Cohort (2004-2006)	226	296	<b>43</b>	15.6 per 100 p-y [95% CI. 11.1, 19.2] by BED	12.3 per 100 p-y [95% CI. 9.7, 16.0]
SATH-CAP Cross-sectional (2005-2006)	190	192	<b>49</b>	19.3 per 100 p-y [95% CI. 12.7, 25.0] by BED	

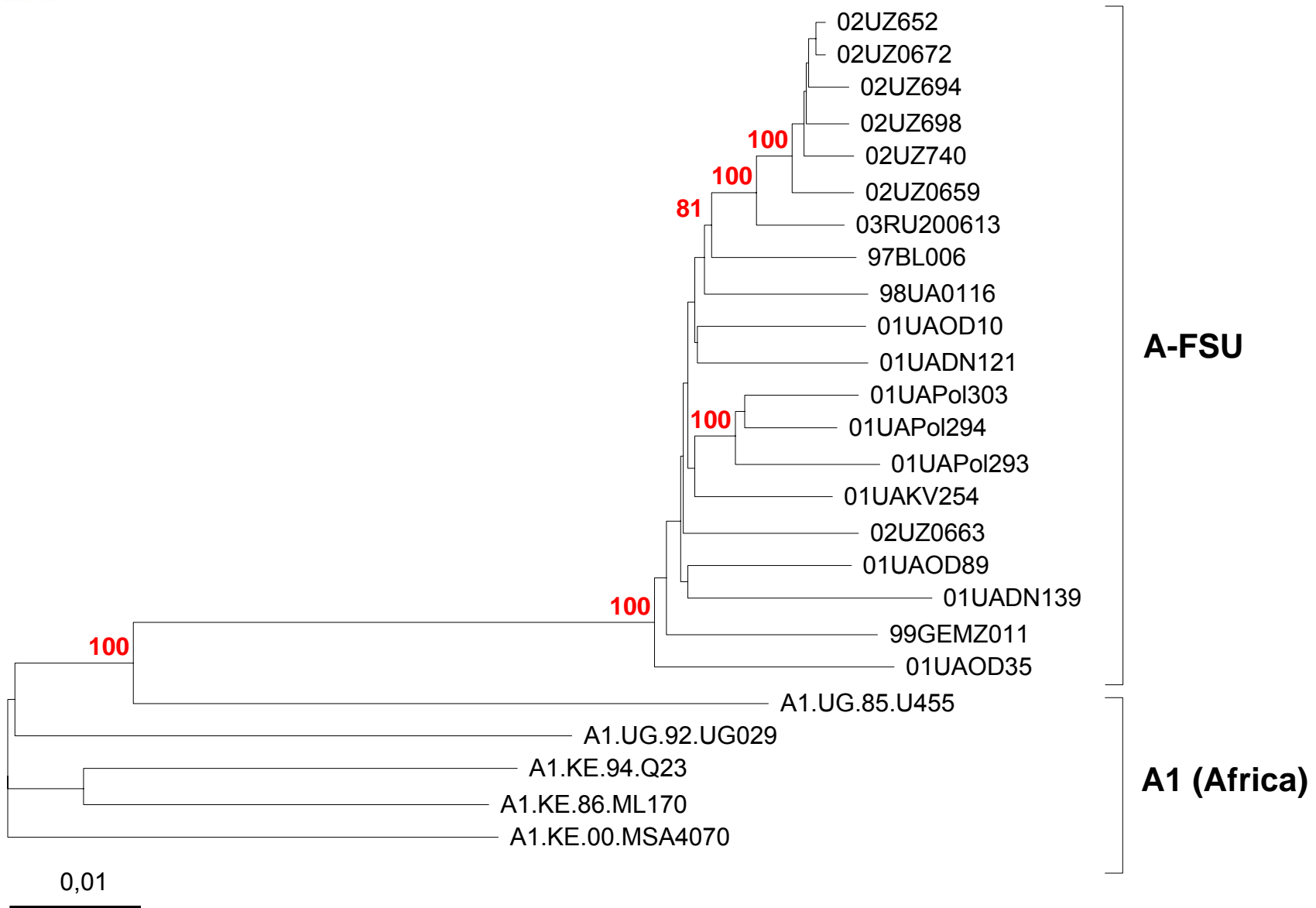


- The HIV epidemic among IDUs in Russia and other the Former Soviet Union countries is caused mainly by HIV-1 subtype A.
- The FSU variant of HIV-1 subtype A is different from the African HIV-1 subtype strains and remarkable for low level of genetic diversity.
- The level of genetic diversity for A-FSU HIV-1 strains in last years remains low.

Studies performed among IDUs in St. Petersburg in 2002 and 2005 discovered low mean *env* genetic distance to the FSU subtype A consensus: 2.1% and 3.7%, respectively.



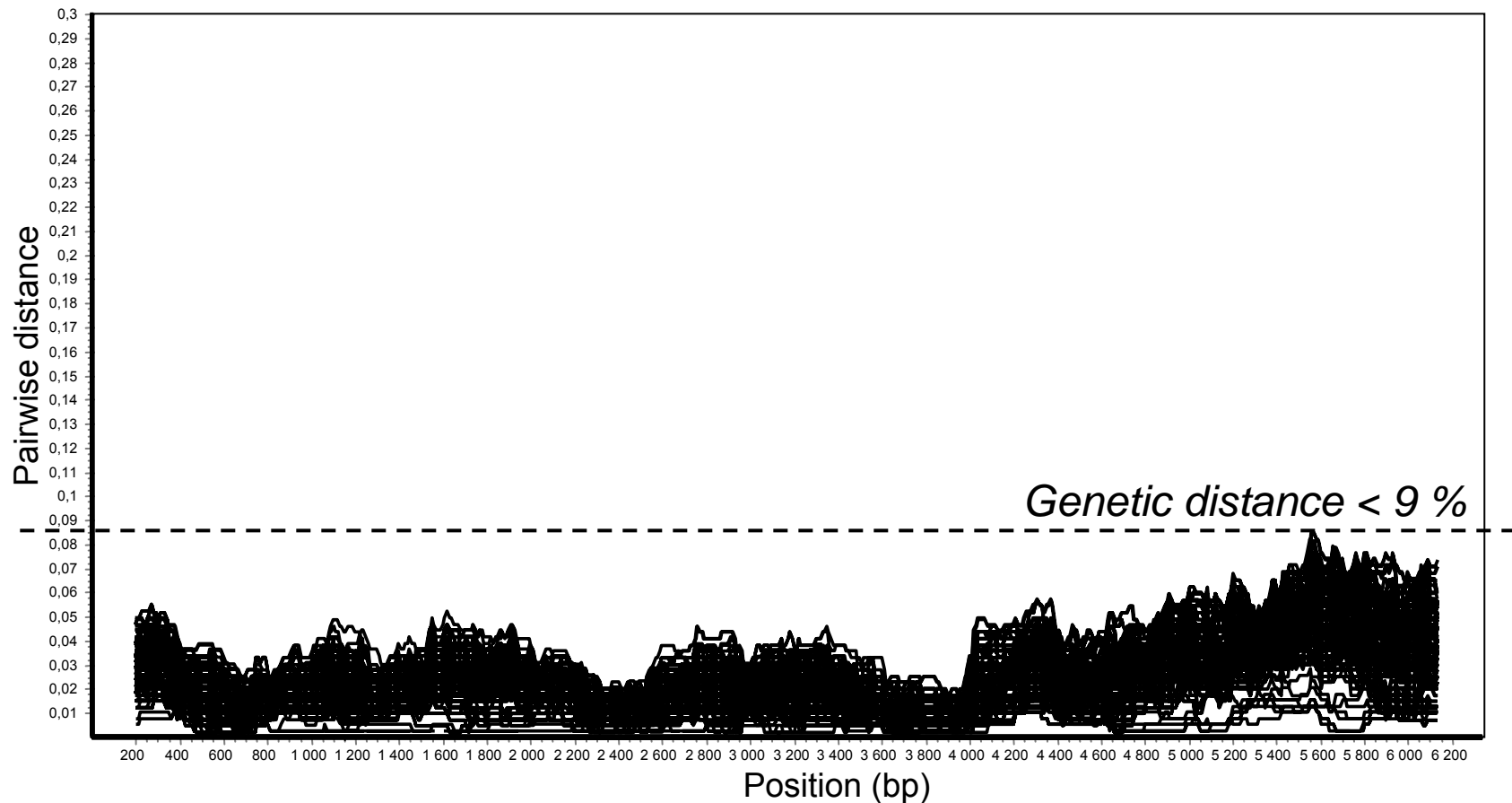
# The full-length genome the FSU subtype A HIV-1 phylogeny





# Full-length genome distance scanning analysis of the FSU subtype A HIV-1 strains

*SimPlot*

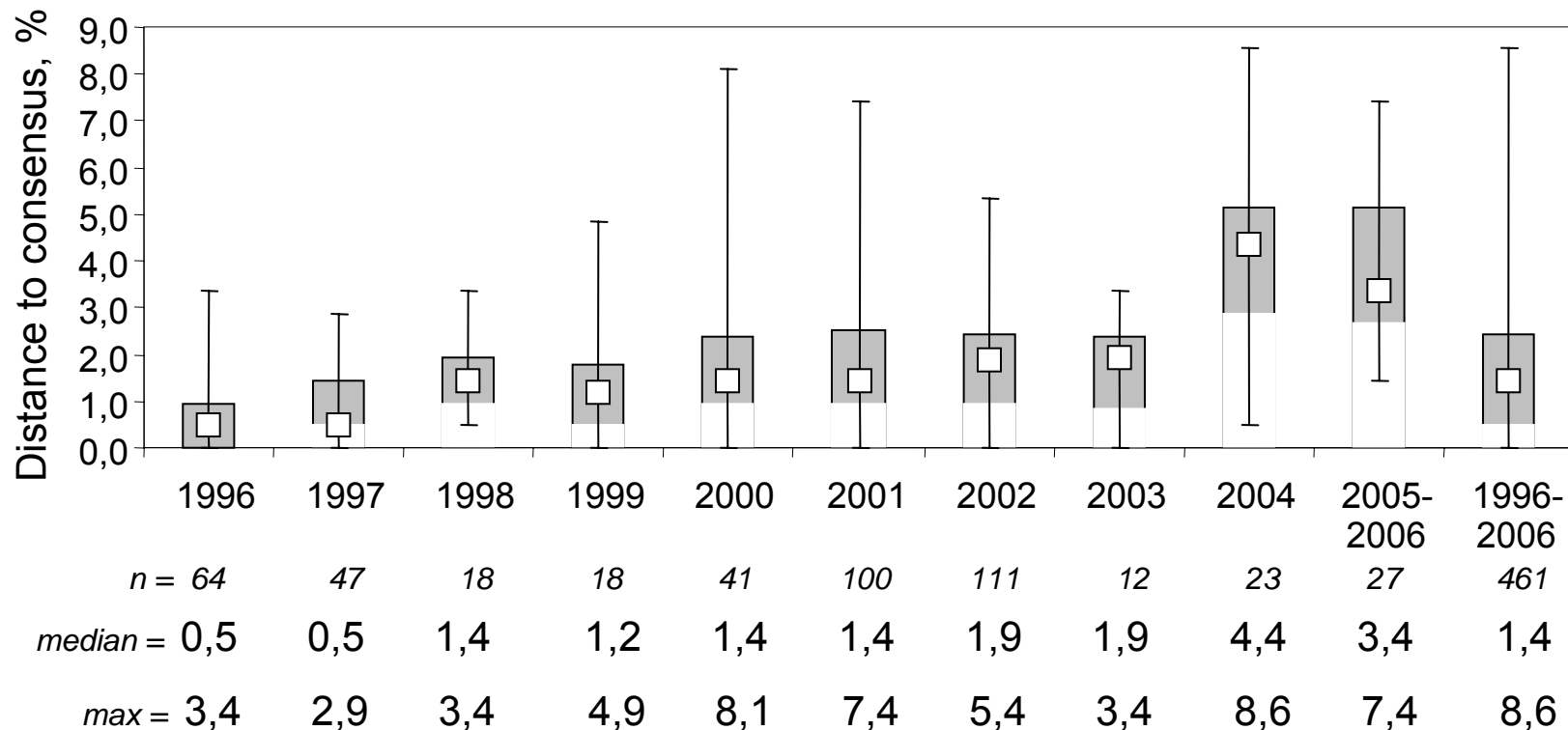


*Window: 400 bp, Step: 10 bp, GapStrip: On, J-C Correction: On*

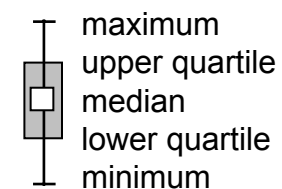


## Genetic diversity of HIV-1 strains collected in the FSU countries in 1996-2006

*env*, 7044-7259 bp of HIV-1<sub>HXB2</sub> genome



461 subtype A (A-FSU) HIV-1 strains: Russia - 215, Ukraine - 53, Belarus - 44, Kazakhstan - 16, Uzbekistan - 25, Moldova - 6, Latvia - 100, Lithuania -1, Georgia -1.





- The search for cases of acute HIV infection (AHI) performed in 2006-2007 has discovered 15 AHI cases among 800 IDUs enrolled in St. Petersburg cohort.
- Single genome analysis (SGA) performed in collaboration with the UNC CFAR revealed very low level of inpatient genetic diversity as compared to chronic HIV infection cases.



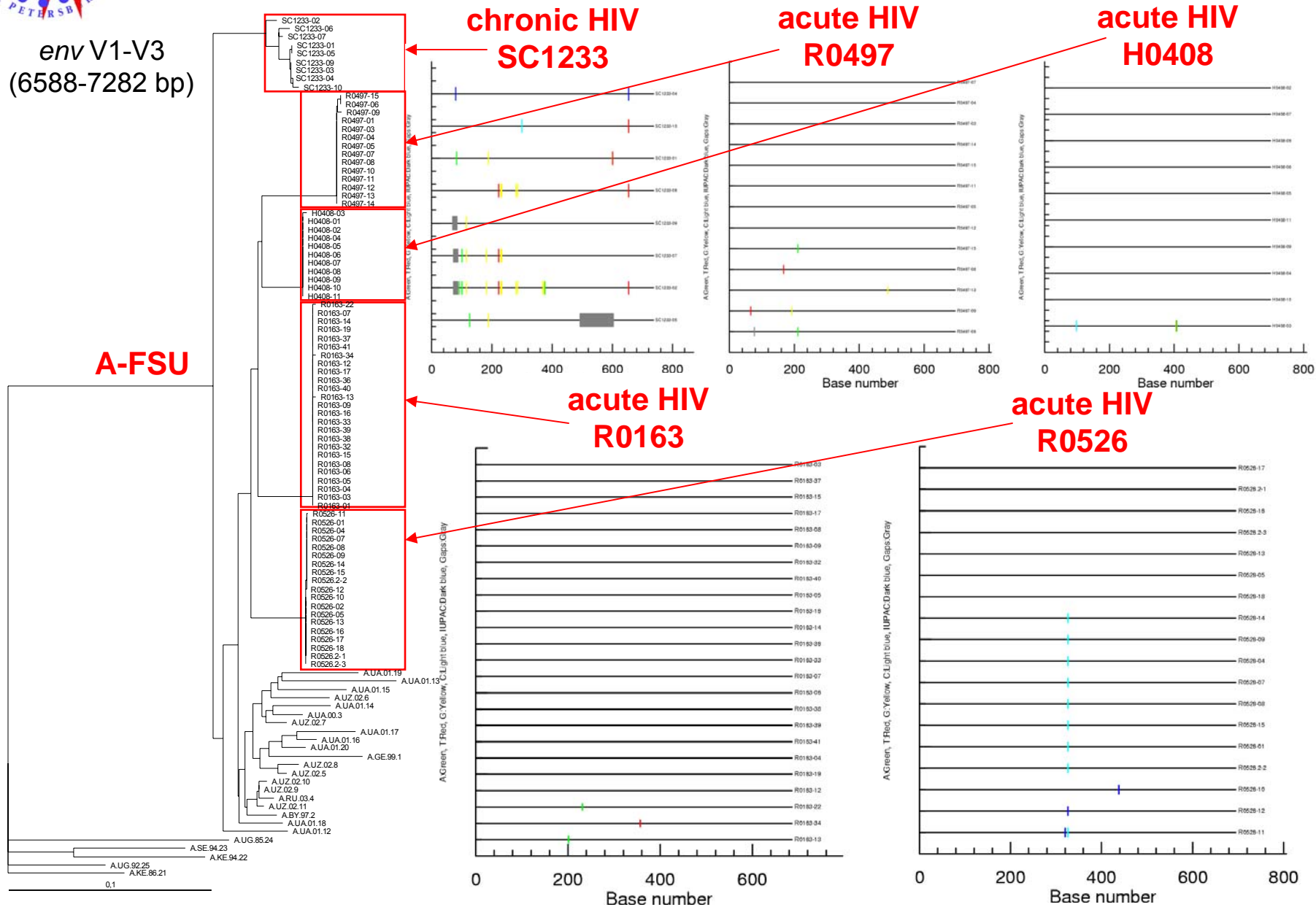
## Detection of acute HIV infection among IDU Participants of Projects at Biomedical Center

Study (Years)	HIV status at screening		Prevalence (%)	Screened for Acute HIV by Roche Amplicor	Number of RNA HIV positives
	Pos	Neg			
HPTN 033 Cohort (2002-2004)	270	620	30	516	6 (all were ELISA positive/ WB indeterminate)
R01 Cohort (2004-2006)	226	296	43	286	9 ( 3 ELISA positive/ WB indeterminate)



# Single genome analysis of acute and chronic cases of HIV infection

env V1-V3  
(6588-7282 bp)

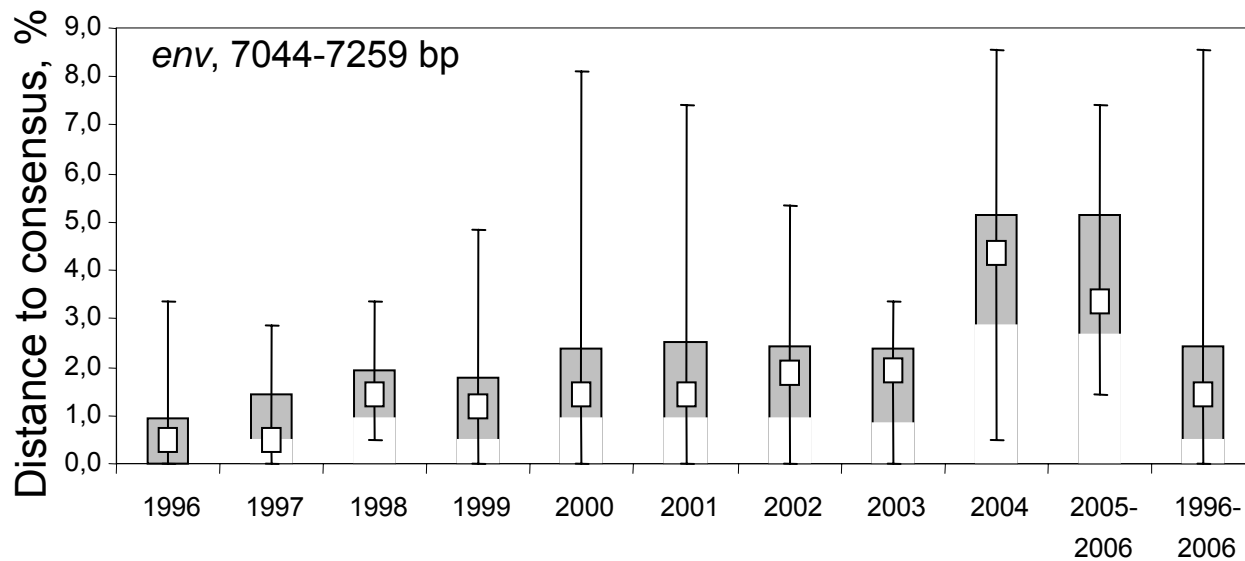
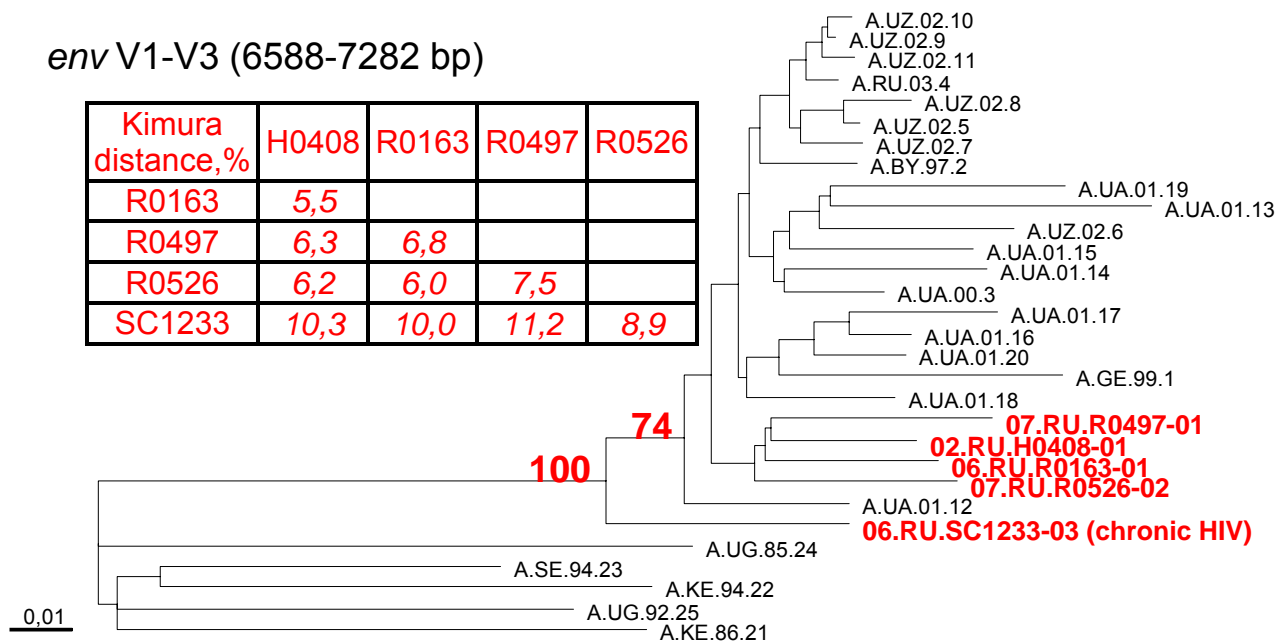




# Interpatient HIV-1 diversity

env V1-V3 (6588-7282 bp)

Kimura distance, %	H0408	R0163	R0497	R0526
R0163	5,5			
R0497	6,3	6,8		
R0526	6,2	6,0	7,5	
SC1233	10,3	10,0	11,2	8,9



Year	Patient	%
★	06.RU.SC1233-03 (chronic HIV)	7,4
★★★	07.RU.R0497-01	4,9
	07.RU.R0526-02	4,9
★	02.RU.H0408-01	3,4
★	06.RU.R0163-01	2,4



**Conclusion: These studies show that incidence of HIV infection among IDU in St. Petersburg has substantially increased during last several years. Different approaches (the cohort study and laboratory testing for incidence cases) produced close results. The current situation of high HIV incidence rates suggests the need for implementation of intense prevention strategies. In the context of a homogeneous infecting HIV strain the situation is also ideal for mounting efficacy trials of HIV vaccines among IDUs in St.Petersburg.**



## Collaborators:

Biomedical center (St.Petersburg, Russia):  
Verevochkin S., Masharsky\*A., Shaboltas\*A.,  
Levchenko\*Yu., Toussova O.

Yale University: Nikkolai L., Heimer R.

Johns Hopkins University: Latkin C., Beyrer C.,  
Baral S.

University of North Carolina: Hoffman I.,  
Swanstrom R.

\*- Former Fogarty trainees

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